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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KOLKER, DANIEL E	
ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,444	ANDERSEN, JULIE K.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-93* is/are pending in the application.

4a) Of the above claim(s) *7-13,24-29,39,41-45,56-61 and 67-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,14-23,30-38,40,46-55 and 62-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-93* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's remarks filed 31 October 2005 have been entered. Claims 1 – 93 are pending.

Election/Restrictions

2. Applicant's election without traverse of Group I and species C (desferrioxamine) in the reply filed on 31 October 2005 is acknowledged.

Applicant asserts that claims 1 – 4, 11 – 20, 27 – 35, 43 – 52, 59 – 79, and 86 – 90 read on the elected species and will be examined in the instant office action. The examiner disagrees. First, it is noted that Group I encompasses claims 1 – 34, 35 – 36 (in part), 37 – 38, and 40 – 66. Thus claims 67 – 79 and 86 – 90 do not read on elected subject matter, contrary to applicant's assertion. Furthermore, claims drawn to methods of administering iron-binding proteins generically and ferritin or subunits thereof in particular, are not reasonably encompassed by the elected species desferrioxamine. The elected species is clearly a small organic molecule and is not an iron-binding protein. Claim 4, which recites desferrioxamine, depends from claim 3, drawn to iron-chelating small organic molecules. The definition of "small organic molecule" provided on p. 7 of the specification explicitly excludes proteins. Thus claims encompassing administration of proteins do not read on the elected species. This includes claims 7 – 13, 24 – 29, 39, 41 – 45, 56 – 62.

3. Claims 7 – 13, 24 – 29, 39, 41 – 45, 56 – 61, and 67 – 93 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 31 October 2005.

4. Claims 1 – 6, 14 – 23, 30 – 38, 40, 46 – 55, 62 – 66 are under examination in the instant office action.

Claim Objections

5. Claims 4, 23, 38, and 55 are objected to because of the following informalities: they recite non-elected species, including clioquinol, deferiprone, and pseudan. Appropriate correction is required.

6. Applicant is advised that should claims 19 – 23 and 30 – 34 be found allowable, claims 51 – 55 and 62 – 66 will be objected to under 37 CFR 1.75 as being a substantial duplicate

thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In this case claims 19 and 51 are identical; the remaining claims are identical except for their dependency, but since the base claims are duplicates the dependent claims are also duplicates.

7. Applicant is advised that should claims 30 – 34 be found allowable, claims 46 – 50 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In this case the claims are exact duplicates of one another.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1 – 6, 14 – 23, 30 – 38, 40, 46 – 55, 62 – 66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration of desferrioxamine to an animal, does not reasonably provide enablement for upregulation of endogenous ferritin or hemoglobin, or for administration of derivatives as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (FED. Cir. 1988).

Claims 4, 23, 38, and 55 all encompass administration of derivatives of the recited small molecules. The term "derivatives" is not explicitly defined in the specification with respect to any of the chelators. The term is very broad and encompasses an essentially unlimited number of molecules, unlimited by structure or function, which can be derived from any of the recited molecules. There is no requirement that the derivatives themselves be chelators, or that they have any particular conserved structure with respect to their parent molecules, or that there be any common structure amongst the derivatives. There are no working examples of administration of derivatives to animals or humans. Given the breadth of the claims, the lack of guidance as to how to make or use the derivatives, and the lack of working examples, it would take undue experimentation in order for a skilled artisan to practice the method commensurate in scope with the claims.

Claim 40, which depends from claim 38, is drawn to those embodiments which upregulate endogenous ferritin or hemoglobin. The specification provides no evidence that the treatments upregulate endogenous ferritin or hemoglobin. The art indicates that desferrioxamine does not upregulate either ferritin or hemoglobin. Acuella et al. (1998. Nephrology Dialysis Transplantation 13:1194-1199) teach that administration of desferrioxamine for 6 weeks does not change hemoglobin levels, and in fact reduces ferritin significantly (see p. 1197, second complete paragraph). Since the specification provides no guidance as to how to perform the method such that either hemoglobin or ferritin levels increase, and the art teaches that neither is increased when desferrioxamine is administered, it would take undue experimentation on the part of the skilled artisan to practice the method as claimed.

10. Claims 1 – 6, 14 – 23, 30 – 38, 40, 46 – 55, 62 – 66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 4, 23, 38, and 55 all encompass administration of derivatives of the recited small molecules. The term "derivatives" is not explicitly defined in the specification with respect to any of the chelators. The term is very broad and encompasses an essentially unlimited number of molecules, unlimited by structure or function, which can be derived from any of the recited

molecules. The specification provides no evidence that applicant performed the claimed method with a derivative.

The instant disclosure of a the specific recited chelators, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co,* 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id at 1170, 25 USPQ2d at 1606." Although the above quotation from Fiers is drawn to DNAs, the same logic can be applied to derivatives as claimed herein. As there is no disclosure of derivatives or methods of administering them in the specification, claims to such undefined molecules cannot be considered adequately described.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1 – 4, 6, 16 – 23, 32 – 38, 40, 48 – 55, and 64 – 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Ben-Shachar et al. (1991. Journal of Neurochemistry 56:1441-1444, cited on IDS filed 12 May 2004).

Ben-Shachar teaches administration of desferrioxamine for prevention on death of dopaminergic neurons. Desferrioxamine is administered into the cerebral ventricle (p. 1442, first column). This constitutes local administration to a nerve tissue; claim 6 does not require local administration to a nerve but rather to a tissue. Ben-Shachar teaches that the method is sufficient to inhibit the progression of an animal model of Parkinson's disease, and that the method mitigates several symptoms of the disease (see Figure 1, for example). The method also attenuates the degree of loss of dopaminergic neurons (see p. 1442, second paragraph under Results). While Ben-Shachar is silent with respect to whether or not the method upregulates endogenous ferritin or hemoglobin, this is an inherent consequence of the method, and since all the method steps are taught claim 40 stands rejected as well.

13. Claims 1 – 6, 14 – 15, 18 – 23, 30 – 31, 33 – 38, 40, 46 – 47, 49 – 55, 62 – 63, and 65 – 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al. (U.S. Patent 5,849,290, issued 15 December 1998).

Brown teaches administration of metal-chelators, including desferrioxamine, for treatment of neurodegenerative disease. See column 5 lines 31 – 40. Brown teaches that the method is suitable for treatment of Parkinson's disease (see column 6 lines 40 – 51). The compound is to be administered by a number of systemic or local routes (column 10 line 10-14). Brown teaches treatment of "patients" generally, and the scope of patients clearly encompasses humans (see for example column 18 lines 37 – 55). Thus the prior art reference teaches administration to humans. While the reference is silent as to whether the method mitigates symptoms of the disease or inhibits the onset or progression of disease, these limitations are inherently met by the method, as they inherently occur upon administration of the agent. Similarly although Brown is silent with respect to whether or not the method upregulates endogenous ferritin or hemoglobin, this is an inherent consequence of the method, and since all the method steps are taught claim 40 stands rejected as well.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel E. Kolker, Ph.D.
December 12, 2005

SHARON TURNER, PH.D.
PRIMARY EXAMINER
12-21-05